

Remarks

Status of the Claims

Claims 21-26 are pending in this application.

Rejections- 35 U.S.C. § 103 (a)

I. Tada et al. and Kleber-Janke et al. do not render the present invention unpatentable.

Claim 21 remains rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Tada et al. in further view of Kleber-Janke et al. The Examiner has maintained the rejection of claim 21 on the grounds that the combination of references allegedly renders the present invention obvious. Specifically, the Examiner asserts that Applicants “[m]ust consider the rejection based upon the combination of references. See MPEP § 2145.” See Office Action mailed June 4, 2003, page 4. Applicants respectfully traverse this rejection on the grounds that the reasons made of record fail to establish a reason for combining the cited art and the combination of references do not render the present invention obvious.

A. The PTO has failed to provide any basis for the desirability of the claimed combination.

In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to combine reference teachings. “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” MPEP § 2143.01 (emphasis in original). The Examiner asserts “[u]sing the combined methods of Tada et al. and Kleber-Janke et al., one of skill would have been motivated and expected success in devising a method for producing a transgenic peanut plant with reduced or undetectable allergen protein content in the seed.” See Office Action, page 5. Applicants respectfully traverse this rejection on the grounds that the Examiner has not provided a reason of record for why it would be desirable to combine the teachings of Tada et al. with Kleber-Janke et al.

A motivation to combine teachings of various references cannot be established by merely implying one of ordinary skill in the art is capable of creating the claimed invention from bits and pieces of the documents of record. MPEP § 2143.01. Nor can the motivation be established by discussing how the teachings of the references may allegedly be combined. MPEP § 2143.01. Identifying ingredients and forms within the teachings of references cannot be equated with a motivation to combine those teachings. Since the Examiner has failed to provide any basis for the desirability of combining the cited references, the rejection is improper. For this reason alone, the rejection should be withdrawn.

The Examiner asserts “[o]ne of ordinary skill in the art would have expected to be successful in identifying a homologous region common to more than more *Ara h* allergen gene.” See Office Action, page 5. Yet, the Examiner has failed to provide a reason why one skilled in the art, absent knowledge of the present invention, would be motivated to identify a homologous region from more than one *Ara h* allergen genes and then clone an identified *Ara h* homologous region in the antisense orientation into a vector for peanut transformation. As neither Tada et al. nor Kleber-Janke et al., alone or together, disclose a method for producing a transgenic peanut plant with reduced or undetectable allergen protein content in the seed, the cited art does not render the present invention unpatentable.

B. The combination of references does not render the present invention obvious.

The Examiner asserts that the combined methods of Tada et al. and Kleber-Janke et al. renders the present invention obvious. Applicants traverse this rejection on the grounds that neither reference discloses a method for producing a transgenic peanut plant with reduced allergen content in the seed. It follows, therefore, that the combination of Tada et al. and Kleber-Janke et al. do not render the present invention obvious.

Neither Tada et al. nor Kleber-Janke et al., alone or together, teach or even suggest identifying a region homologous to more than one *Ara h* gene and then cloning the homologous *Ara h* region in the antisense orientation for peanut transformation. The

Examiner is specifically directed to the fact that Tada et al. discloses “14-16 kDa allergens are multigene products” and “[m]ore than 10 homologous cDNA clones encoding the 14-16 kDa allergens have been identified” (*See* Tada et al., page 341, first column). Yet, despite this explicit disclosure, Tada et al. neither teaches nor suggests identifying a region homologous to more than one allergen for cloning in the antisense orientation. In fact, Tada et al. teaches a single clone denoted as RA17(*See* Tada et al., page 341, second column) for cloning in the antisense orientation. The Examiner even admits “Tada et al. do not teach identifying a homologous region common to more than one *Ara h* allergen gene or peanut transformation...” *See* Office Action, page 7. Furthermore, Kleber-Janke et al. neither teaches nor suggests identifying a region homologous to more than one *Ara h* gene and transforming a peanut with an antisense *Ara h* construct. While Kleber-Janke et al. may have identified regions homologous to more than one *Ara h* gene, nowhere does the reference discuss transforming a peanut plant with an antisense *Ara h* gene, let alone a region homologous to more than one *Ara h* gene. As one would expect from an article published in *International Archives of Allergy and Immunology*, Kleber-Janke et al. only discloses the sequence of *Ara h* genes in the context of IgE-binding properties and patient reactivity profiles, not in the context of transgenic plants having reduced allergen content. Therefore, even if the Examiner had established a motivation to combine the references, the combination of references would not render the instant invention obvious. Again, for this reason alone, the rejection should be withdrawn.

While Tada et al. may use antisense technology for reducing 14-16 kDa proteins in rice, neither Tada et al. nor Kleber-Janke et al. disclose a method for producing a transgenic peanut plant with reduced allergen content in the seed. The Examiner even admits “[t]he Examiner has misstated that Tada et al. teaches that the antisense approach could be used in other crop plants containing known allergens such as peanuts and soybeans....” *See* Office Action, page 4. At most, Tada et al. discloses that antisense may be applicable to crop plants, but the disclosure of a genus does not necessarily render each species within that genus *prima facie* obvious. *See In re Jones*, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992). The genus of crop plants is too large to inherently describe every member within it. *Cf.* MPEP § 2144.08 II. A 4

a. "Some motivation to select the claimed species or subgenus must be taught by the prior art." *Id.* Yet Tada et al. fails to identify any crop plant. The silence of Tada et al. cannot provide a motivation to select any particular species. Since neither Tada et al. nor Kleber-Janke et al. disclose a method for producing a transgenic peanut plant with reduced allergen content, the combination of references do not render the present invention obvious.

C. An obviousness rejection can not be based upon unqualified hindsight reasoning.

To prevent the use of hindsight based on the invention to defeat patentability of an invention, the Federal Circuit requires the PTO to show a motivation to combine the references that create the case of obviousness. In other words, the PTO must show reasons that the skilled artisan, confronted with the same problems as the inventor and lacking knowledge of the claimed invention, would choose the elements from the cited references for combination in the manner claimed. *In re Rouffet*, 47 USPQ2d 1453, 1457-8 (Fed. Cir. 1998). Importantly, with respect to this motivation, the Federal Circuit placed the burden on the PTO to present "clear and particular" evidence showing motivation to combine. *In re Dembiczak*, 50 USPQ.2d 1614 (Fed. Cir. 1999).

Since the Examiner has not established a motivation or desirability for combining the teachings of the references, the Examiner has merely used Applicants' specification as a hindsight road map to recreate the claimed invention. To prevent the use of hindsight, "[t]he initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done." *See* MPEP § 2142. That has not been done in this case.

II. Tada et al., in view of Kleber-Janke et al. and Lacorte et al, do not establish a prima facie case of obviousness.

Claims 21-23 and 25-26 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Tada et al., in view of Kleber-Janke et al. and Lacorte et al. Applicants respectfully traverse this rejection.

The Examiner cites Lacorte et al. to allegedly remedy the deficiencies of Tada et al. and Kleber-Janke et al. Specifically, the Examiner asserts “Lacorte et al. teach gene transfer into peanut plants via *Agrobacterium tumefaciens* is an efficient way to introduce desirable traits into crop plants.” See Office Action, page 7. For the reasons discussed above, neither Tada et al. nor Kleber-Janke et al. disclose a method for producing a transgenic peanut plant with reduced allergen content. Moreover, neither reference, alone or together, disclose a method for identifying a region homologous to more than one *Ara h* gene and introducing said homologous *Ara h* region, in antisense orientation, into a recipient peanut cell. Since Lacorte et al., alone or in combination with Tada et al. and Kleber-Janke et al., does not disclose a method for identifying a region homologous to more than one *Ara h* gene and transforming a peanut plant with an antisense *Ara h* homologous region, Lacorte et al. does not remedy the deficiencies of the cited art. Accordingly, the present invention is not unpatentable over Tada et al., in view of Kleber-Janke et al. and Lacorte et al. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.

III. Tada et al., in view of Kleber-Janke et al. and Klein et al., do not establish a prima facie case of obviousness.

Claims 21-22 and 24-26 are rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over Tada et al. and Kleber-Janke et al. as applied to claims 21-23 and 25-26 above and in further view of Klein et al. Applicants respectfully traverse this rejection.

The Examiner cites Klein et al. to allegedly remedy the deficiencies of Tada et al. and Kleber-Janke et al. Specifically, the Examiner asserts “Klein teach introducing nucleic acids into a plant cell using high velocity biolistic penetration by small particles is an alternative

approach to the restricted *Agrobacterium tumefaciens* transformation method.” See Office Action, page 9. As discussed above, neither Tada et al. nor Kleber-Janke et al. disclose a method for producing a transgenic peanut plant with reduced allergen content. Moreover, neither reference, alone or together, disclose a method for identifying a region homologous to more than one *Ara h* gene and introducing said homologous *Ara h* region, in antisense orientation, into a recipient peanut cell. By the same token, Klein et al., alone or in combination with Tada et al. and Kleber-Janke et al., does not disclose a method for identifying a region homologous to more than one *Ara h* gene and transforming a peanut plant with an antisense *Ara h* homologous region. Consequently, Klein et al. does not remedy the deficiencies of Tada et al. and Kleber-Janke et al.. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

In summary, none of the cited references, alone or together, disclose a method for identifying a region homologous to more than one *Ara h* gene and transforming a peanut plant with an antisense *Ara h* homologous region. As a result, there is no *prima facie* case of obviousness established with respect to claims 21-26.

CONCLUSION

As the above-presented amendments and remarks address and avoid all of the rejections presented by the Examiner, withdrawal of the rejections and allowance of the claims are respectfully requested. No new matter has been added.

If there are any questions concerning this application, the Examiner is courteously invited to contact the undersigned counsel.

Respectfully submitted,

Date September 25, 2003

By Richard Peet

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Telephone: (202) 672-5569
Facsimile: (202) 672-5399

Richard Peet
Attorney for Applicant
Registration No. 35, 792

Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.